REMARKS

Claims 44 - 80 are presently pending in this application.

Response to Claim Rejections – 35 USC §112

Claim 66 was rejected under 35 USC 112, second paragraph as being indefinite. Claim 66 has been amended so that rejection is now considered moot.

Response to Claim Rejections 35 USC §103

Claims 44, 55, 62, 66 and 70- 71 were rejected under 35 USC 103(a) as being unpatentable over Burgess in view of Holden.

Statement of 35 U.S.C. 103

It is well established that the Examiner has the initial burden of establishing a prima facie case of obviousness. See *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984); *In re Rinehart,* 531 F.2d 1048, 1051 (CCPA 1976).

For a prima facie case of obviousness to be established there must be "an apparent reason to combine the known elements in the fashion claimed." *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740-41 (2007)

That prima facie case must be clear and convincing. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). MPEP 706.02(j).

The motivation relied upon by the Examiner must not come solely from the description of the Applicant's invention in their specification. If it does, the Examiner used impermissible hindsight when rejecting the claims. See *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1553, (Fed. Cir. 1983); *In re Rothermel,* 276 F.2d 393, 396 (CCPA 1960).

Claimed Invention:

Claim 44 includes the limitations of an orthotic foot support device having

1) a thin flexible ***stretch-resistant*** sole member of uniform thickness ***having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole***; and

2) an adhesive layer on the sole member for ***securely adhering*** the device directly to an outer skin tissue on the sole of the foot,

3) a protective cover removably disposed over said adhesive layer which, when removed, exposes said adhesive layer;

4) the ***stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue*** on the sole of a foot, when adhered thereto, and

5) said adhesive layer of ***sufficient adhesion to maintain the stretch-resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, the adhesive layer, and the sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia.***

Rejection under 35 USC 103

The Office Action stated:

> Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin, flexible and conformable lining; with respect to the limitation of "stretch resistant" Burgess' device (110) is both flexible and conformable to the foot. The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50 – 55). Also Burgess discloses the liner will remain on the foot to allow mobility while still having increased adhesion as a greater effective contact surface area is provided (abstract). Applicant sets forth in the disclosure of the invention that the stretch resistant device" is a sufficiently flexible article with adhesive lining and that adhesive on the sole of the linings when the lining is on the surface of the foot imparts at least some restriction to extension and stretching of the tissue. The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's line is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess

meets this claimed limitation. The device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot form about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2).
Burgess does not disclose that the foot protector can be formed into different sizes or cuts to fit by the wearer. However, Holden teaches a protective attachment that removably attaches to the bottom of the foot (abstract) that is easily trimmed to fit the size and shape of the body part [0003]. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to form the device of Burgess into different sizes or cuts to fit by the wearer, as taught by Holden to fit various size of feet and to cover whole or partial as user desire.

References

Burgess discloses a "***Disposable Foot Protector***" to protect the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations (Summary of the Invention).

Holden discloses a "***Protective Attachment***" for to protect the bottom of the foot from rough terrain, hot sands and pavement without wearing a shoe sandal or otherwise having interfering ties or straps that go between the toes or over the foot. (Summary of the Invention).

Differences between Burgess and limitations of claim 44

Orthotic Device

Claim 44 includes the limitation of an "orthotic device. The device, as set forth in claim 44, includes structural limitations that establish it's function as an orthotic. Orthotic is commonly defined, such as by Merriam-Webster Dictionary as "1) of or relating to orthotics; 2) designed for the support of weak or ineffective joints or muscles." Alternatively, orthotic is commonly defined, such as found on MedicineNet.com in the medical terms dictionary section as "A support, brace or splint used to support, align, prevent or correct the function of movable parts of the body. Shoe inserts are orthotics that intended to correct an abnormal, or irregular walking pattern, by altering slightly the angles at which the foot strikes a walking or running surface. Other orthotics include neck braces, lumbosacral supports, knee braces and wrist supports". (See Exhibit F).

Orthotic has never been defined as a protector for protecting the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations. An orthotic device is not used as a replacement for footwear, but is used in combination with footwear.

The device of Burgess clearly discloses that it is to be used in lieu of ordinary footwear to protect the foot from surfaces of indeterminate cleanliness and temperature fluctuations. It does not disclose, suggest or teach any use as an orthotic device and is incapable of operating as an orthotic device.

Stretch-Resistance

"This is particularly the case when a fibrous layer is used as the ***resilient*** sheet member". Column 3, lines 35 – 37. "Further, this allows increased mobility as the ***foot protector 100 is able to adjust of flexing of the foot during normal walking or running movements without inhibiting foot movement*** or causing the tack adhesive to tear away from the foot." Column 3, lines 46 – 50. "Preferably, the fibers are randomly oriented to provide a ***good degree of resilience*** and flexibility." Column 4, lines 8 -10.

Claim 44 includes the limitation of an orthotic device that has a ***stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue.***

Burgess teaches away from this limitation in that the foot protector is resilient and able to stretch during movement so not limit the movement of the foot. The device of Burgess would not function as intended if it was stretch resistant.

The Office Action stated: "The device comprises a thin, flexible and conformable lining; with respect to the limitation of "stretch resistant" Burgess' device (110) is both flexible and conformable to the foot." This does not address the limitation of the orthotic device being stretch resistant. Clearly, Burgess does not teach or suggest the use of a stretch resistant material. Indeed, Burgess teaches just the opposite, a foot protector that can stretch so that is does not inhibit the flexing of the foot during movement.

Adhesive Strength

The foot protector of Burgess is a resilient sheet member 110 of substantially uniform thickness with a tack adhesive layer. The tack adhesive layer 120 is "sticky enough to reliably hold the

foot protector **100** against the foot **200**, but ***is not so sticky that it causes difficulty or discomfort in removing the foot protector 100 from the sole of the foot 200***. The ***easier*** it is to remove the foot protector **100** from the sole of the foot **200**, the ***more the wearer can experience the comfort level*** of a conventional slipper." Column 3, lines 2 – 8.

Claim 44 includes the limitation of an adhesive layer that has ***sufficient adhesion to maintain the stretch-resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, the adhesive layer, and the sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia***.

Burgess actually teaches away from this limitation as the adhesive strength of the adhesive layer is intended to allow increased mobility of the protector 100 to adjust to flexing of the foot ***without inhibiting foot movement***. The orthotic device of claim 44 defines limitations to ***restrict extension and stretching of an outer skin tissue*** in order to prevent excessive tensile stress in a plantar fascia.

The Office Action stated that: "The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's line is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation." This is not supported by the disclosure of Burgess. Burgess teaches just the opposite, that the adhesive layer and stretchability of the foot protector will not inhibit movement and flexing of the foot during movement. Burgess teaches using an adhesive of low tack strength so the foot protector is easy to use and will not inhibit the movement of the foot. The present invention, as presently claimed, is just the opposite, it is intended to inhibit the movement of the foot to prevent excessive stress on the plantar fascia.

Size and Shape

> Changes in mere size or shape in some circumstances may be considered obvious combinations or modification, but would not be considered obvious in the case where doing so would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then

there is no suggestion or motivation to make the proposed modification." (MPEP 2143.01)

Claim 44 includes the limitation of ***"having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole".*** Burgess includes ***"a resilient sheet member of substantially uniform thickness, and having a shape generally matching a shape of a sole of a foot and generally corresponding in size to the foot."*** To modify Burgess as required to meet the limitation of claim 44 would destroy its intended function ***"to protect the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations"***(Summary of the Invention).

Burgess, teaches away from ***"having a shape matching less than the entire sole of the foot"*** or being ***"sized to cover only a portion of the foot"*** as found in claim 44. Instead Burgess teaches ***"a resilient sheet member of substantially uniform thickness, and having a shape generally matching a shape of a sole of a foot and generally corresponding in size to the foot'.***

To combine Burgess with Holden to produce a device which covers only a portion of the sole of the foot would in this case destroy the functionality taught by Burgess, and thus would not be a permissible combination. There simply is no reason to consider it obvious to modify Burgess into an orthotic device as set forth in claim 44 without using the Applicant's specification as a guideline for doing so.

Objective Evidence of Nonobviousness

Satisfying a Long Felt Need

The present invention as set forth in the claims solves a long felt need by providing a solution not previously provided by other attempts.

1) The treatment of plantar fasciitis has long been a problem. See Exhibits A – D for representative articles from the Mayo Clinic and from other reputable sources.

2) This problem has not been solved by others. See Exhibits A – D, the treatments for this problem involve: a) rest; b) stretching; c) thick insoles; d) anti-inflammatory medication. None of the prior art cited by the examiner or found in the literature discuss using a non-stretching adhesive sole member adhered to the sole of the foot.

3) The presently claimed invention solves this problem. See Declaration of Dr. Delamos, Exhibit E. The declaration clearly provides a nexus between the success of the problem (plantar fasciitis) and the unique features of the claimed invention (stretch resistant sole portion with a strong adhesive layer that restricts the extension and stretching of the outer skin tissue).

According to MPEP 716.01 (a): "The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976)."

This objective evidence is dispositive of the nonobviousness of the presently claimed invention. A key limitation found in the claims of a "stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue on the sole of a foot, when adhered thereto" provides the nexus between the ability of the product of the claimed invention to satisfy the long felt need of treating plantar fasciitis as set forth in the declaration of Dr. Delamos.

Summary

The present invention, as set forth in claim 44, sets for limitations of an orthotic device that is able to treat and prevent plantar fasciitis by limiting the movement of the foot to prevent excessive stress on the plantar fascia. These limitations include a thin stretch-resistant sole member that has a strong adhesive layer so that the movement of the foot is restricted. Burgess on the other hand is directed to foot protector to protect the foot from surfaces of indeterminate cleanliness and temperature fluctuations. It is intended to simulate a comfortable slipper and

allows free movement of the foot without limitation. There simply is no reason to consider it obvious to modify Burgess into an orthotic device as set forth in claim 44 without using the Applicant's specification as a guideline for doing so.

The disclosure of Holden of trimming a protective foot cover to fit the shape of the wearer's foot fails to remedy the failure of Burgess to teach an orthotic device that has a thin stretch-resistant sole member with a strong adhesive layer to limit the movement of the foot to prevent excessive stresses on the plantar fascia.

The objective evidence of nonobviousness further is dispositive of the patentability of the presently claimed inventon.

Claim 62

Claim 62 sets forth a method for restricting extension and stretching of the plantar fascia of a human foot, comprising the steps of:

1) providing a thin flexible device of substantially uniform thickness having a stretch-resistant sole member sized and shaped to be conformed to an outer skin tissue on at least a portion of a sole of a wearer's foot in a region of the foot from a heel of a foot to a distal end of the toes, excluding the region under the four smaller toes; and

2) an adhesive layer on at least a portion of said sole member for adhering said device to the outer skin tissue on the sole of a wearer's foot, said adhesive layer of sufficient adhesive strength to maintain said device in place on the outer skin tissue on the sole of the foot and said stretch-resistant sole engaging surface sufficiently stretch-resistant so as to restrict extension and stretching of the outer skin tissue when adhered thereto;

adhering said sole member to an outer skin tissue on a portion of a sole of a foot such that tension forces applied to the plantar fascia are shared with said device outer skin tissue, said adhesive layer and said sole member to restrict extension and stretching of an outer skin tissue on a sole of a foot, whereby; preventing excessive stress on a plantar fascia.

Neither the device of Burgess or Holden provide any steps of adhering a stretch-resistant sole member to the outer skin tissue on the sole of a wearer's foot to restrict extension and stretching of the outer skin tissue to prevent excessive stress on a plantar fascia. There simply is no reason to modify the devices of Burgess or Holden to arrive at the claimed invention without using the guidance of Applicant's specification.

Additionally, the Burgess reference teaches away from, ***"excluding the region under the four smaller toes"*** as Burgess is intended to protect the foot from contact with surfaces of indeterminate cleanliness and temperature fluctuations. Burgess states that it may be slightly larger or slightly smaller than the size of the foot, but has an outline generally matching the shape the foot, thus not excluding any region of the foot from being protected ***"from contact with surfaces of indeterminate cleanliness and temperature fluctuations"***. Excluding a region of Burgess would allow contact of the foot to the floor surfaces thus would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. (MPEP 2143.01)

Claim 66

Claim 66 includes the limitations of claim 62 with the added limitation of ***"adhering opposed ends of a thin flexible strap extending laterally outward from opposite sides of said stretch-resistant sole member to the outer skin tissue on a side or a top of a foot to provide a further means for maintaining said sole member in engagement with a sole of a foot;*** *and wherein said device is used for the treatment or prevention of plantar fasciitis".*

Neither Burgess or Holden, disclose such a limitation nor teach or suggest a reason which would motivate one to add such a feature or step to their devices. Additionally, Holden teaches away from straps ***"without wearing a shoe sandal or otherwise having interfering ties or straps that go between the toes or over the foot".*** Further, the combination of references fails to teach a device ***"used for the treatment or prevention of plantar fasciitis"***, thus failing to meet all the limitations of the claim.

Claim 70

Claim 70 includes the limitations of an orthotic foot support device for reducing stress on the plantar fascia of a wearer's foot, said device comprising:

a stretch resistant, uniform thickness sole support, having a shape matching less than an entire outline of a sole of an individual's foot where the device is to be applied;

an adhesive layer on said sole support for attaching said sole support to a sole of the wearer's foot such that said sole support absorbs tensile stress thus preventing extension and stretching of tissue on a bottom of the wearer's foot on which a said sole support is attached, whereby preventing excessive tensile stress in a plantar fascia.

As discussed in the response to the rejection of claim 44, neither Burgess or Holden disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia and actually teach away from such a device. There simply is no reason to consider it obvious to modify Burgess into an orthotic device as set forth in claim 70 without using the Applicant's specification as a guideline for doing so.

Response to the rejection of claims 48 -54 and 56 – 65

Claims 48 – 54 and 56 – 65 were rejected as being unpatentable over Burgess and Holden in view of Domenico.

Claims 48 – 54 include the limitations of claim 44 plus the additional limitation of a thin flexible arch strap having opposed ends extending laterally outward from opposite sides of the stretch-resistant sole member with an adhesive layer to adhere to an outer skin tissue on a side or top of an arch of the foot.

The Office Action restated the earlier rejection using the combination of Burgess and Holden and further acknowledged that neither Burgess nor Holden disclose thin flexible straps extending laterally outward from the opposite sides of the stretch-resistant sole member to adhere to a side or top of an arch of the foot. The Office Action cites Domenico as teaching a support device for prevention of ankle injuries having thin flexible straps extending laterally outward from opposite sides to partially encircle the talus, the navicular, the cuniform and the cubiod region of the foot, an arch strap and a heel strap.

Domenico fails to disclose an orthotic device for treating plantar fascia nor does Domenico disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. None of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. There simply is no reason to consider it obvious to modify Burgess into an orthotic device as set forth in claims 48 – 54 without using the Applicant's specification as a guideline for doing so.

Claims 56 – 65 also include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts

stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as at least one thin flexible strap or tab extending outward from the sole member beyond a sole of the foot with an adhesive layer to adhere directly to a skin surface on a side or top of the foot. As discussed above, Burgess, Holden and Domenico, either taken singly in combination with one another disclose, teach or suggest an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. These references actually teach away from the claimed invention as they disclose devices that allow flexible movement of the lower heel rather restricting movement as necessary in the current invention.

The Office action stated that in respect to claims 44, 56, and 60,

> "the limitations of "restricting extension and stretching of the outer skin tissue on the sole of the foot", when the device described above adheres to sole, it will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user's foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot."

There is no support for this conclusion. Burgess is explicit that the sole member is able to stretch to allow free and normal movement of the foot rather than restricting the movement of the foot. "Further, this allows increased mobility as the foot protector 100 is able to adjust of flexing of the foot during normal walking or running movements without inhibiting foot movement or causing the tack adhesive to tear away from the foot." Column 3, lines 46 – 50. "Preferably, the fibers are randomly oriented to provide a ***good degree of resilience*** and flexibility." Column 4, lines 8 -10.

Burgess teaches away from restricting the extension and stretching of the outer skin tissue, as clearly shown.

Response to rejection of claims 45, 72, 75-76, 78 and 80

Claims 45, 72, 75 – 76, 78 and 80 were rejected in view of the combination of Burgess and Holden in view of Desnoyers.

Claims 45, 72, 75, 76, 78 and 80 include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the sole member having a ration of elongation to tensile strength that is less than .9.

The Office Action repeated the earlier combination of Burgess and Holden, and alleged that it would be obvious to use the teaching of Desnoyers of a pressure sensitive tape having a ratio of elongation to tensile strength ratio of about 3 to 1 as meeting the limitations. Desnoyers fails to disclose, suggest or teach an orthotic device that has a stretch resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia. **Desnoyers actually teaches away from such a device as shown in column 4, lines 67 – 70 "These tapes, preferably, have an extensibility at break of 45% or more in the lengthwise direction". Further, as disclosed in claim 1 of Desnoyers, column 7, lines 3 – 4, "tape having a relatively high longitudinal extensibility", Desnoyers clearly teaches away from the presently claimed invention**. Even if it would be obvious to use the teaching of Desnoyers, this combination would not begin to disclose the presently claimed invention.

None of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. There simply is no reason to consider it obvious to modify Burgess into an orthotic device as set forth in claims 45, 72, 75, 76, 78 and 80 without using the Applicant's specification as a guideline for doing so.

Response to rejection of claims 46 and 55.

Claims 46 and 55 were rejected as unpatentable over Burgess and Holden.

Claims 46 and 55 include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the sole member being formed of a single layer of fabric material having a uniform thickness of less than 30 mil. (0.762 mm).

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden clearly disclose foot protectors that provide cushioning for comfort. These references teach away from the use of a thin sole member of less than 30 mils as it would not provide adequate cushioning for comfort and thus would destroy the functioning of the reference, or make it unsatisfactory for its intended purpose. (MPEP 2143.01). Additionally, these references are not formed of a single layer of fabric and, thus the proposed combination fails to teach all claim limitations.

There simply is no reason to consider it obvious to modify the cited references into an orthotic device as set forth in claims 46 and 55 without using the Applicant's specification as a guideline for doing so.

Response to rejection of claims 47, 61, 67 and 69

Claims 47, 61, 67 and 69 were rejected as unpatentable over the combination of Burgess and Holden in view of Huddleston et al.

Claims 47, 61, 67 and 69 include the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as the sole member exhibiting less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch.

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden teach away from a sole member that is stretch resistant, as discussed above. Huddleston et al. teaches a metal foil adhesive for use with rigid fiberglass air ducts that has a tensile strength greater than 25 pounds/inch. However, Huddleston et al. fails to disclose whether or not the metal foil adhesive exhibits less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch. Thus Huddleston et al. fails to disclose this critical limitation, thus the proposed combination fails to teach all claim limitations.

Additionally, the claimed invention does not include a metal foil. The exclusion of the metal foil would destroy the functionality of the Huddleston reference making it unsatisfactory for its intended purpose. (MPEP 2143.01)

There simply is no reason to consider it obvious to modify cited references into an orthotic device as set forth in claims 47, 61, 67 and 69 without using the Applicant's specification as a guideline for doing so.

Response to rejection of claim 68

Claim 68 was rejected as unpatentable over Burgess, Holden and Huddleston et al. Claim 68 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as a sole member having a single layer of fabric with adhesive layer having a thickness of less than 30 mils and exhibiting less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch.

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden teach away from a sole member that is stretch resistant, as discussed above. Huddleston et al. teaches a metal foil adhesive for use with rigid fiberglass air ducts that has a tensile strength greater than 25 pounds/inch. However, Huddleston et al. fails to disclose whether or not the metal foil adhesive exhibits less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch. Thus Huddleston et al. fails to disclose this critical limitation.

There simply is no reason to consider it obvious to modify cited references into an orthotic device as set forth in claim 68 without using the Applicant's specification as a guideline for doing so.

Response to rejection of claims 73 – 74

Claims 73 – 74 were rejected as being unpatentable in view of the combination of Burgess, Holden and Desnoyers. Claims 73 - 74 includes the limitations of an orthotic foot

support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as a sole member having a woven micro-fiber layer or being less than 30 mils.

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden clearly disclose foot protectors that provide cushioning for comfort. These references teach away from the use of a thin sole member of less than 30 mils as it would not provide adequate cushioning for comfort. (MPEP 2144.05).

Neither of the references teach the use of a woven micro-fiber, thus the combination of references fails to meet this claim limitation. Instead Burgess teaches using a resilient sheet material designed to provide cushioning. This is in direct conflict with the claimed limitations of the present invention. There simply is no reason to consider it obvious to modify the cited references into an orthotic device as set forth in claims 73 and 74 without using the Applicant's specification as a guideline for doing so.

Response to rejection of claims 77 and 79

Claims 77 and 79 were rejected as unpatentable over Burgess, Holden and Desnoyers in view of Huddleston et al. Claims 77 and 79 includes the limitations of an orthotic foot support device having a thin flexible substantially stretch-resistant sole member having an adhesive layer that restricts stretching and extension of an outer skin tissue to prevent excessive or damaging tensile stress in a plantar fascia as well as a sole member having a single layer of fabric with adhesive layer having a thickness of less than 30 mils and exhibiting less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch.

As discussed above, none of the references taken in either singly or in combination with one another teach, suggest or disclose an orthotic device having a stretch resistant layer with a strong adhesive layer to prevent extension and stretching of tissue to prevent excessive tensile stress in a plantar fascia. Further, both Burgess and Holden teach away from a sole member that is stretch resistant, as discussed above. Huddleston et al. teaches a metal foil adhesive for use

with rigid fiberglass air ducts that has a tensile strength greater than 25 pounds/inch. However, Huddleston et al. fails to disclose whether or not the metal foil adhesive exhibits less than 15% elongation when subjected to a tensile load equivalent to 25 pounds/inch. Thus Huddleston et al. fails to disclose this critical limitation. Additionally, these references are not formed of "***a single layer of fabric***" and, thus the proposed combination again fails to teach all claim limitations.

There simply is no reason to consider it obvious to modify cited references into an orthotic device as set forth in claims 77 and 79 without using the Applicant's specification as a guideline for doing so.

Summary

None of the references, taken singly or combination with one another disclose, suggest or teach an orthotic device that has a thin sole member that is stretch-resistant and that has an adhesive layer that will prevent the outer skin to which it is adhered from extending to prevent excessive stresses on the plantar fascia. Burgess and Holden specifically teach away from such a device in that their foot protectors enable the foot to move without restriction.

Further, the present invention as set forth in the claims solves a long felt need by providing a solution not previously provided by other attempts.

1) The treatment of plantar fasciitis has long been a problem. See Exhibits A – D for representative articles from the Mayo Clinic and from other reputable sources.

2) This problem has not been solved by others. See Exhibits A – D, the treatments for this problem involve: a) rest; b) stretching; c) thick insoles; d) anti-inflammatory medication. None of the prior art cited by the examiner or found in the literature discuss using a non-stretching adhesive sole member adhered to the sole of the foot.

3) The presently claimed invention solves this problem. See Declaration of Dr. Delamos, Exhibit E. The declaration clearly provides a nexus between the success of the problem (plantar fasciitis) and the unique features of the claimed invention (stretch resistant sole portion with a strong adhesive layer that restricts the extension and stretching of the outer skin tissue).

According to MPEP 716.01 (a): "The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be

considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder,* 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976)."

This objective evidence is dispositive of the nonobviousness of the presently claimed invention. A key limitation found in the claims of a "stretch-resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue on the sole of a foot, when adhered thereto" provides the nexus between the ability of the product of the claimed invention to satisfy the long felt need of treating plantar fasciitis as set forth in the declaration of Dr. Delamos.

These claims are believed to be in condition for allowance. Applicant respectfully request that this amendment be entered and that a timely Notice of Allowance be issued in this case.

The Examiner is respectfully requested to telephone the undersigned if further discussions would advance the prosecution of this application.

Respectfully submitted,

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